

Applicant: Christian Knöpfle et al.

Serial No.: 09/921,233

Group Art Unit: 3738

Page 2 of 2

REMARKS

After entry of the subject amendment, claims 1-6, 8-12, and 28 remain pending in the subject application. More specifically, claims 1, 6, and 12 have been amended, claim 7 has been cancelled, and claim 28 has been added. There is full support in the specification as originally filed for the amendments to the claims (*as described below in the discussion of the amendments to independent claims 1 and 12*). There is also full support for the added claim. Accordingly, no new matter has been introduced.

Claims 1-6 and 12 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hair (United States Patent No. 6,197,037). Furthermore, claims 1 and 7-9 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Wellisz et al. (United States Patent No. 6,168,596), and claims 9 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wellisz et al. in view of Pohndorf et al. (United States Patent No. 5,904,683). The Applicant respectfully submits that these rejections are obviated and that the pending claims are allowable in view of the amendments to independent claims 1 and 12.

Both independent claims 1 and 12 have been amended to further clarify the patentable features of the subject invention relative to the spike. More specifically, claims 1 and 12 have been amended to clarify that the spike, which is supported by the extension, extends substantially parallel to the support element toward the bone cover or bone fragment. Both of these claims have also been amended to further require that the spike have a substantially triangular form.

There is clear support in the original specification for these amendments. For example, with respect to the amendment of the extension of the spike substantially parallel to the support element, in Figure 1, the spike is illustrated as extending substantially parallel to the support element. Furthermore, on page 4, lines 12-19, it is described that it is preferred for the spike to extend “substantially parallel to the support element” for reliable driving of the spike into the bone cover or bone fragment. This adequately anchors the

Applicant: Christian Knöpfle et al.

Serial No.: 09/921,233

Group Art Unit: 3738

Page 2 of 2

implant. It is also described that the spike may also be somewhat inclined relative to the support element, yet still be substantially parallel to the support element such that the spike can still be driven into the bone cover or bone fragment to a sufficient depth. The degree of incline can, therefore, vary. With respect to the amendment of the spike having a substantially triangular form, in Figures 1 and 2, the spike is illustrated as being tapered, i.e., having a substantially triangular form. Furthermore, in original claim 7 and on page 6, lines 12-13, it is described that it is preferred for the spike to have a "triangular structure."

As a result of the amendments to independent claims 1 and 12, it is now clear that with the spike extending substantially parallel to the support element and with the spike having a substantially triangular form, the spike can be driven laterally into the bone cover or bone fragment. As described throughout the specification, such driving of the spike into the bone cover or bone fragments is important because it ensures adequate anchoring of the implant.

In view of the amendments to independent claims 1 and 12, it is now clear that the '037 patent to Hair does not anticipate the invention as now claimed. Although, as the Examiner notes, Hair discloses a self-retaining implant for attaching a bone cover or bone fragment that includes a support element having an upper side and a lower side that faces a surface of the bone cover or bone fragment and an extension extending from the lower side of the support element, *it does not* disclose, teach, or otherwise suggest the at least one spike as now claimed in the amended claims. More specifically, if elements 60L and 60R of Hair are the at least one spike, then these elements do not include a substantially triangular form such that the spike can be driven laterally into the bone cover or bone fragment. In fact, the elements 60L and 60R of Hair are not even driven into any bone component whatsoever. Instead, referring to Figures 2-6 of Hair, the elements 60L and 60R, which are blunt, i.e., not tapered, are always disposed below the inner cortical cone 16 and are not actually driven into the inner cortical bone 16. Furthermore, if it was attempted to drive the non-triangular elements 60L and 60R of

Hair laterally into the bone cover or bone fragment, they would actually destroy the bone cover or bone fragment. As a result, the self-retaining implant disclosed in Hair is similar to the disadvantageous self-retaining implants described on page 2, lines 15-23 in the Description of the Prior Art. As stated in the original specification, such self-retaining implants are awkward to handle and have a tendency to damage the flaps of the meninges.

In view of the amendments to independent claims 1 and 12, it is now clear that the '596 patent to Wellisz et al. does not anticipate the invention as now claimed. Although, as the Examiner notes, Wellisz et al. discloses a self-retaining implant that includes the elements of original, i.e., unamended, claim 1, *it does not* disclose, teach, or otherwise suggest the at least one spike as now claimed in the amended claims. More specifically, the element of Wellisz et al. considered to be the spike, specifically the element 23a, does not extend substantially parallel to the support element. Instead, the spike element 23a extends angularly downward from the support element (*refer to Figures 5-9*). As such, the spike element 23a of Wellisz et al. does not extend toward the bone cover or bone fragment and cannot, therefore, be driven laterally into the bone cover or bone fragment. In fact, the spike element 23a of Wellisz et al. is resilient and flexes (*refer to column 4, lines 41-45 of the '596 patent*). Due to this flexibility, and also because the spike element 23a does not extend substantially parallel to the support element, the spike element 23a is merely able to engage bone and cannot be driven laterally into the bone cover or bone fragment to adequately anchor the implant.

At this point, it is important to note that even a combination of the disclosure and teachings the '037 patent and the '596 patent would not render the amended claims obvious because even upon such a combination, there would be no disclosure, teaching, or suggestion of a self-retaining implant that includes at least one spike extending substantially parallel to a support element and having a substantially triangular form such that the spike can be driven laterally into the bone cover or bone fragment. Neither of

Applicant: Christian Knöpfle et al.
Serial No.: 09/921,233
Group Art Unit: 3738
Page 2 of 2

the spikes in the '037 patent or the '596 patent are able to be driven laterally into the bone cover or bone fragment.

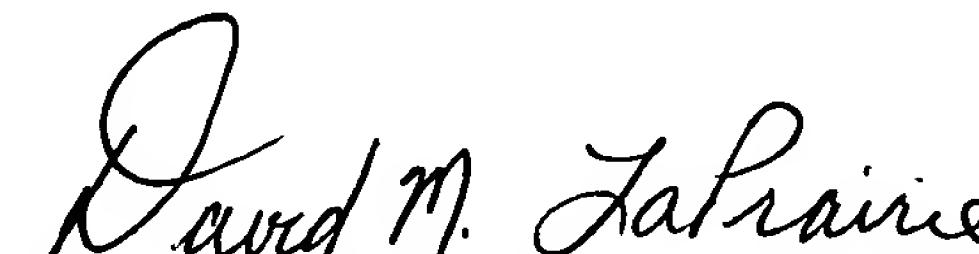
In view of the amendments to independent claims 1 and 12 as well as the arguments set forth above, it is respectfully submitted that the § 102(e) and § 103(a) rejections are obviated and that the application is presented in condition for allowance, which allowance is respectfully solicited.

No fees are believed to be due. However, if necessary, the Commissioner is authorized to charge Deposit Account No. 08-2789 for any additional fees or to credit the account for any overpayment.

Respectfully submitted,

HOWARD & HOWARD ATTORNEYS, P.C.

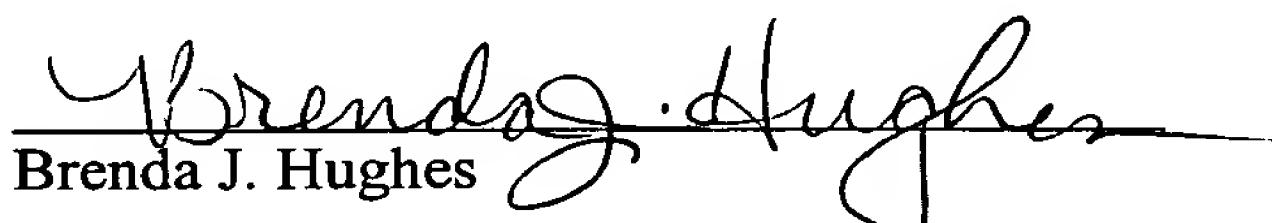
Date: May 5, 2003



David M. LaPrairie, Reg. No. 46,295
The Pinehurst Office Center, Suite 101
39400 Woodward Avenue
Bloomfield Hills, MI 48304-5151
(248) 723-0442

CERTIFICATE OF MAILING

I hereby certify that the attached **Amendment** for Serial Number 09/921,233, filed August 1, 2001, is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to the **Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450**, on **May 5, 2003**.



Brenda J. Hughes

Applicant: Christian Knöpfle et al.
Serial No.: 09/921,233
Group Art Unit: 3738
Page 2 of 2

REC'D 16 MAY 2003

MAY 16 2003

TECHNOLOGY CENTER R3700



VERSION OF CLAIMS WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please replace claims 1, 6, and 12 with the following:

1. (Twice Amended) A self-retaining implant for attaching a bone cover or a bone fragment, the implant comprising:

a support element having an upper side and a lower side, the lower side for facing a surface of the bone cover or the bone fragment; and

an extension extending from the lower side of the support element and supporting therefrom at least one spike, wherein the spike extends substantially parallel to the support element [which extends towards] toward the bone cover or bone fragment and has a substantially triangular form such that the spike [and] can be driven laterally into the bone cover or bone fragment.

6. (Twice Amended) The implant according to Claim 1, wherein the spike [is] extends from an end of the extension remote from the support element.

Please cancel claim 7.

Applicant: Christian Knöpfle et al.

Serial No.: 09/921,233

Group Art Unit: 3738

Page 2 of 2

12. (Twice Amended) A self-retaining implant for attaching a bone cover or a bone fragment to a skull, the implant comprising:

a support element with an upper side and a lower side for contacting the bone cover or the bone fragment, and

an extension[,] extending from the lower side of the support element in such a manner that the support element and the extension form a T-shaped structure in cross section, the extension supporting at least one spike[,] which extends [essentially] substantially parallel to the support element toward the bone cover or bone fragment and has a substantially triangular form such that the spike [and] can be driven laterally into the bone cover or bone fragment.